



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Subhashis Banerjee et al.

Serial No.: 10/623,035

ART UNIT: 1643

Filed: July 18, 2003

EXAMINER: David J. Blanchard

Entitled: : TREATMENT OF PAIN USING
TNFALPHA INHIBITORS

Attorney Docket No.: BBC-206

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING

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December 5, 2005
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Daphne Miller
Daphne Miller

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.56, 1.97 AND 1.98

Sir/Madam:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 for the above-identified application. Applicants makes the following publications of record in the above-identified application.

U.S. Patent Documents

Salfeld et al., July 18, 2000, U.S. Patent No. 6,090,382

Salfeld et al., July 10, 2001, U.S. Patent No. 6,258,562

Salfeld et al., January 21, 2003, U.S. Patent No. 6,509,015

Foreign Patent Documents

Kempeni et al., December 19, 2002, WO 02/100330
Fischkoff et al., January 15, 2004, WO 2004/004633
Krause et al., February 26, 2004, WO 2004/016286
Kaymakcalan et al., May 6, 2004, WO 2004/037205
Salfeld et al., August 14, 1997, WO 97/29131

Other Publications

Aloe et al., *Psychopharmacology (Berl)*. 1997 Dec; 134(3): 287-292.
Bennett and Xie, (1988) *Pain*. 33: 87-107.
Coelho et al., *Am J Physiol Gastrointest Liver Physiol*. 2000 Oct; 279(4): G781-G790.
Coelho et al., *Brain Res Bull*. 2000 Jun; 52(3): 223-228.
Cunha et al., *Br J Pharmacol*. 1992 Nov., 107(3): 660-664.
Empl et al., *Neurology*. 2001 May 22; 56(10): 1371-1377.
Huygen et al., *Mediators Inflamm*. 2002 Feb; 11(1): 47-51.
Ignatowski et al., *Brain Res*. 1999 Sep 11; 841(1-2): 70-77.
Kim and Chung, (1992) *Pain* 50: 355-363
Lindenlaub and Sommer (2003) *Acta Neuropathol (Berl)*. 105:593
Lindenlaub et al., *Brain Res*. 2000 Jun 2; 866(1-2): 15-22.
Myers, *Regional Anesthesia* (1995) 20:173-184
Old, L. *Science* (1985) 230: 630-632
Olmarker et al., *Spine*. 2001 Apr 15; 26(8): 863-869.
Parada et al., *Eur J Neurosci*. 2003 May; 17(9): 1847-1852.
Sagara et al., *Diabetologia*. 1996 Mar; 39(3): 263-269.
Schafers et al., *Neurosci Lett*. 2001 Sep 14; 310(2-3): 113-116.
Schafers et al., *J Neurosci*. 2003 Apr 1; 23(7): 3028-3038.
Sommer et al., *Brain Res*. 2001 Sep 14; 913(1): 86-89.
Sommer et al., *J Peripher Nerv Syst*. 2001 Jun; 6(2): 67-72.
Sommer et al., *Exp Neurol*. 1998 May; 151(1):138-142.
Sommer, C., *Schmerz* (1999) 13(5): 315-23.
Sorkin et al., *Neuroscience*. 1997 Nov; 81(1): 255-262.
Watkins et al., *Brain Res*. 1994 Aug 15; 654(1): 15-26.
Zimmermann, *Eur J Pharmacol*. 2001 Oct 19; 429(1-3): 23-37.

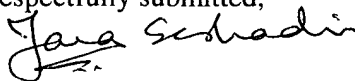
Form PTO-1449 listing each of these documents and photocopies of each document are enclosed herewith for the Examiner's convenience.

This paper is being mailed before the mailing of a first Office action. Pursuant to 37 CFR §1.97(b)(4), no fee is required with this submission.

Applicant does not intend to represent that any of the documents submitted herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicant respectfully requests that the documents submitted herein be considered and made of record in this application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Tara Seshadri". The signature is fluid and cursive, with a horizontal line underlining the name.

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Substitute Form 1449/PTO

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of 4

Application Number

10/623.035

Filing Date

July 18, 2003

First Named Inventor

S. Banerjee

Art Unit

1643

Examiner Name _____

David J. Blanchard

Attorney Docket Number

BBC-206

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	4	WO 02/100330	12-19-2002	Abbott Biotechnology Ltd.		
	5	WO 04/004633	01-15-2004	Abbott Biotechnology Ltd.		
	6	WO 04/016286	02-26-2004	Abbott Biotechnology Ltd.		
	7	WO 04/037205	05-06-2004	Abbott Biotechnology Ltd.		
	8	WO 97/29131	08-14-1997	BASF Aktiengesellschaft		

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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		Application Number	10/623,035		
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		First Named Inventor	S. Banerjee		
		Art Unit	1643		
		Examiner Name	David J. Blanchard		
Sheet	2	of	4	Attorney Docket Number	BBC-206

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Aloe et al., "Role of TNF-alpha but not NGF in murine hyperalgesia induced by parasitic infection". Psychopharmacology (Berl). 1997 Dec; 134(3): 287-292.	
		Bennett and Xie, "A peripheral mononeuropathy in rat that produces disorders of pain sensation like those seen in man". (1988) Pain. 33: 87-107.	
		Coelho et al., "Systemic lipopolysaccharide influences rectal sensitivity in rats: role of mast cells, cytokines, and vagus nerve". Am J Physiol Gastrointest Liver Physiol. 2000 Oct; 279(4): G781-G790.	
		Coelho et al., "Brain interleukin-1 β and tumor necrosis factor- α are involved in lipopolysaccharide-induced delayed rectal allodynia in awake rats". Brain Res Bull 2000 June, 52(3): 223-228.	
		Cunha et al., "The pivotal role of tumour necrosis factor alpha in the development of inflammatory hyperalgesia." Br J Pharmacol. 1992 Nov., 107(3): 660-664.	
		Empl et al., Neurology. "TNF-alpha expression in painful and nonpainful neuropathies." 2001 May 22; 56(10): 1371-1377.	
		Huygen et al., "Evidence for local inflammation in complex regional pain syndrome type 1." Mediators Inflamm. 2002 Feb;11(1): 47-51.	
		Ignatowski et al., "Brain-derived TNFalpha mediates neuropathic pain." Brain Res. 1999 Sep 11; 841(1-2): 70-77.	
		Kim and Chung, "An experimental model for peripheral neuropathy produced by segmental spinal nerve ligation in the rat." (1992) Pain 50: 355-363	
		Lindenlaub and Sommer, "Cytokines in sural nerve biopsies from inflammatory and non-inflammatory neuropathies." (2003) Acta Neuropathol (Berl). 105:593	

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Sheet 3 of 4	Attorney Docket Number		BBC-206

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		Lindenlaub et al., "Effects of neutralizing antibodies to TNF α on pain-related behavior and nerve regeneration in mice with chronic constriction injury." Brain Res. 2000 Jun 2; 866(1-2): 15-22.	
		Myers, R., "The Pathogenesis of Neuropathic Pain." Regional Anesthesia (1995) 20(3):173-184.	
		Old, L., "Tumor Necrosis Factor (TNF)." (1985) Science 230: 630-632	
		Olmarker et al., "Selective Inhibition of Tumor Necrosis Factor- α Prevents Nucleus Pulposus-Induced Thrombus Formation, Intraneural Edema, and Reduction of Nerve Conduction Velocity." Spine. 2001 Apr 15; 26(8): 863-869.	
		Parada et al., "Tumor necrosis factor receptor type-1 in sensory neurons contributes to induction of chronic enhancement of inflammatory hyperalgesia in rat." Eur J Neurosci. 2003 May; 17(9): 1847-1852.	
		Sagara et al., "Inhibition of development of peripheral neuropathy in streptozotocin-induced diabetic rats with N-acetylcysteine." Diabetologia. 1996 Mar; 39(3): 263-269.	
		Schafers et al., "Combined epineurial therapy with neutralizing antibodies to tumor necrosis factor- α and interleukin-1 receptor has an additive effect in reducing neuropathic pain in mice." Neurosci Lett. 2001 Sep 14; 310(2-3): 113-116.	
		Schafers et al., "Increased Sensitivity of Injured and Adjacent Uninjured Rat Primary Sensory Neurons to Exogenous Tumor Necrosis Factor α after Spinal Nerve Ligation J Neurosci. 2003 Apr 1; 23(7): 3028-3038.	
		Sommer et al., "Anti-TNF-neutralizing antibodies reduce pain-related behavior in two different mouse models of painful mononeuropathy." Brain Res. 2001 Sep 14; 913(1): 86-89.	
		Sommer et al., "Etanercept reduces hyperalgesia in experimental painful neuropathy." J Peripher Nerv Syst. 2001 Jun; 6(2): 67-72.	

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Sheet 4 of 4

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		Sommer et al., "Hyperalgesia in Experimental Neuropathy Is Dependent on the TNF Receptor 1." Exp Neurol. 1998 May; 151(1):138-142	
		Sommer, C. "Animal studies on neuropathic pain: the role of cytokines and cytokine receptors in pathogenesis and therapy." Schmerz . (1999) 13(5): 315-323.	
		Sorkin et al., "Tumour necrosis factor-alpha induces extopic activity in nociceptive primary afferent fibres." Neuroscience. 1997 Nov; 81(1): 255-262.	
		Watkins et al., "Characterization of cytokine-induced hyperalgesia." Brain Res. 1994 Aug 15; 654(1): 15-26.	
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